# Exhibit "4"

Gynecare
TVT™

Tension-free Support
for Incontinence

**GYNECARE TVT™**
**Tension-free Vaginal Tape**

**D**
GYNECARE TVT Implantat – Einweg
GYNECARE TVT Einführungsinstrument – wiederverwendbar
GYNECARE TVT Metall Katheter-Führung – wiederverwendbar

**DK**
Sterilt GYNECARE TVT bånd til engangsbrug
GYNECARE TVT Indfører til flergangsbrug
Stiv GYNECARE TVT guidewire til flergangsbrug

**E**
Dispositivo de un solo uso GYNECARE TVT
Introductor reutilizable GYNECARE TVT
Guía rígida reutilizable para el catéter GYNECARE TVT

**F**
Dispositif GYNECARE TVT à usage unique
Introducteur GYNECARE TVT réutilisable
Guide de sonde rigide GYNECARE TVT réutilisable

**FIN**
GYNECARE TVT nauha, kertakäyttöinen
GYNECARE TVT toistokäyttöinen sisäänviejä
GYNECARE TVT toistokäyttöinen jäykkä katetrinohjain

**GB**
GYNECARE TVT Single Use Device
GYNECARE TVT Reusable Introducer
**USA**
GYNECARE TVT Reusable Rigid Catheter Guide

**GR**
Συσκευή μιας χρήσης GYNECARE TVT
Εισαγωγέας GYNECARE TVT πολλαπλής χρήσης
Ω ςΧ ς GYNECARE TVT

**I**
Dispositivo GYNECARE TVT monouso
Introduttore poliuso per dispositivo GYNECARE TVT
Guida rigida poliuso per catetere GYNECARE TVT

**NL**
GYNECARE TVT instrument voor éénmalig gebruik
GYNECARE TVT reusable inbrenghandvat
GYNECARE TVT reusable cathetervoerder

**P**
Dispositivo GYNECARE TVT – Uso único
Introdutor GYNECARE TVT – Reutilizável
Guia rígida de cateter GYNECARE TVT – Reutilizável

**S**
GYNECARE TVT nålar med inkontinensband för engångsbruk
GYNECARE TVT handtag för flergångsbruk
GYNECARE TVT kateterguide för flergångsbruk

CE 0086

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Gynecare
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RMC P 15506/E

GB USA **Tension-free Vaginal Tape (GYNECARE TVT) System – Instructions For Use**

**GYNECARE TVT Single Use Device**
**GYNECARE TVT Reusable Introducer**
**GYNECARE TVT Reusable Rigid Catheter Guide**

**Please read all information carefully.**
Failure to properly follow instructions may result in improper functioning of the device and lead to injury.

**Important:**
This package insert is designed to provide instructions for use of the Tension-free Vaginal Tape single use device, reusable introducer, and reusable rigid catheter guide. It is not a comprehensive reference to surgical technique for correcting Stress Urinary Incontinence (SUI). The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence and specifically in implanting the GYNECARE TVT device. These instructions are recommended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

**DESCRIPTION (System)**
GYNECARE TVT consists of the following:
- GYNECARE TVT Single Use Device, provided sterile (available separately)
- GYNECARE TVT Reusable Introducer, provided non-sterile (available separately)
- GYNECARE TVT Reusable Rigid Catheter Guide, provided non-sterile (available separately)

**GYNECARE TVT DEVICE**
The GYNECARE TVT device is a sterile single use device, consisting of one piece of undyed or blue (Phthalocyanine blue, color index. Number 74160) PROLENE® polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm), covered by a plastic sheath cut and overlapping in the middle, and held between two stainless steel needles bonded to the mesh and sheath with plastic collars.

PROLENE® polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE® polypropylene non-absorbable surgical suture. The mesh is approximately 0.027 inches (0.7 mm) thick. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE® mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

**GYNECARE TVT INTRODUCER**
The GYNECARE TVT introducer is provided non-sterile and is reusable. The introducer is made of stainless steel. It consists of two parts, a handle and an inserted threaded metal shaft. The introducer is intended to facilitate the passage of the GYNECARE TVT device from the vagina to the abdominal skin. It is connected and fixed to the needle, via the threaded end of the shaft, prior to inserting the needle with the tape.

**GYNECARE TVT RIGID CATHETER GUIDE**
The GYNECARE TVT rigid catheter guide is a non-sterile reusable instrument intended to facilitate the identification of the urethra and the bladder neck during the surgical procedure. It is inserted into a Foley catheter (recommended size 18 French) positioned in the bladder via the urethra. To facilitate insertion, it can be lubricated with gel.

**INDICATIONS**
The GYNECARE TVT device is intended to be used as a pubourethral sling for treatment of Stress Urinary Incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The GYNECARE TVT introducer and rigid catheter guide are available separately and are intended to facilitate the placement of the GYNECARE TVT device.

**INSTRUCTIONS FOR USE**

The patient should be placed in the lithotomy position taking care to avoid hip flexion greater than 60°.

The procedure can be carried out under local anesthesia, but it can also be performed using regional or general anesthesia. The extent of dissection is minimal, i.e., a vaginal midline entry with a small paraurethral dissection to initially position the needle and two suprapubic skin incisions. Using forceps, grasp the vaginal wall at each side of the urethra. Using a small scalpel, make a sagittal incision about 1.5 cm long starting approximately 1.0 cm from the outer urethral meatus. This incision will cover the mid-urethral zone and will allow for subsequent passage of the sling (tape). With a small pair of blunt scissors, two small paraurethral dissections (approximately 0.5 cm) are made so that the tip of the needle can then be introduced into the paraurethral dissection. Then, two abdominal skin incisions of 0.5-1 cm are made, one on each side of the midline just above the symphysis not more than 4-5 cm apart. Incision placement and needle passage near the midline and close to the back of the pubic bone are important to avoid anatomic structures in the inguinal area and lateral pelvic sidewall.

The GYNECARE TVT rigid catheter guide is inserted into the channel of the Foley catheter (18 French). The handle of the guide is fixed around the catheter, proximal to its widening. The purpose of the guide is to move the bladder neck and urethra away from where the tip of the needle will pass into the retropubic space. Via use of the Foley catheter and the rigid catheter guide, the urethra and bladder are moved contralaterally to the side of the needle passage. During this maneuver, the bladder should be empty. The threaded end of the introducer is screwed into the end of one of the needles.

Using the introducer, the needle is passed paraurethrally penetrating the urogenital diaphragm. Insertion and passage are controlled by using the long or index finger in the vagina under the vaginal wall on the ipsilateral side and fingertip control on the pelvic rim. The curved part of the needle should rest in the palm of the "vaginal" hand. If you are right-handed, this means that the left hand generally is the one to be used for needle guidance. With the other hand, grip the handle of the introducer gently. Now introduce the needle tip into the retropubic space. Once again, observe that this should be done by the palm of the vaginal hand and with the needle tip horizontally, i.e., in the frontal plane. After passage of the urogenital diaphragm you will feel that the resistance is significantly reduced.

Immediately aim the tip of the needle towards the abdominal midline and lower the handle of the introducer, thereby pressing the tip of the needle against the back of the pubic bone. Now move the needle tip upwards to the abdominal skin incision, keeping in close contact with the pubic bone all the way.

When the needle tip has reached the abdominal incision, cystoscopy is performed to confirm bladder integrity. The bladder must be emptied after the first cystoscopy. The procedure is then repeated on the other side. The needles are then pulled upward to bring the tape (sling) loosely, i.e., without tension, under the midurethra. Cut the tape close to the needles. Now, adjust the tape so that leakage is reduced allowing a few drops of urinary leakage to occur under stress. For this, use patient feedback, i.e., coughing with a full bladder (approximately 300 mL) and keep the vaginal incision temporarily closed by a gentle grip with small forceps. The plastic sheaths that surround the tape are then removed. To avoid putting tension on the tape, a blunt instrument (scissors or forceps) should be placed between the urethra and the tape during removal of the plastic sheaths. Premature removal of the sheath may make subsequent adjustments difficult. After proper adjustment of the tape, close the vaginal incision. The abdominal ends of the tape are then cut and left in subcutis. Do not suture them. Suture the skin incisions. Empty the bladder. Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2-3 hours after the operation.

**CONTRAINDICATIONS**

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE® polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

**WARNINGS AND PRECAUTIONS**

- Do not use GYNECARE TVT procedure for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in implanting the GYNECARE TVT system before employing the GYNECARE TVT device. It is important to recognize that GYNECARE TVT is different from a traditional sling procedure in that the tape should be located without tension under mid-urethra.
- Acceptable surgical practice should be followed for the GYNECARE TVT procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimize risks.
- Retropubic bleeding may occur postoperatively. Observe for any symptoms or signs before releasing the patient from the hospital.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- The rigid catheter guide should be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley catheter.
- When removing the rigid catheter guide, open the handle completely so that the catheter remains properly in place.
- Do not remove the plastic sheath until the tape has been properly positioned.
- Ensure that the tape is placed with minimal tension under mid-urethra.
- PROLENE® Mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material.
- The patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical experience is available with vaginal delivery following the GYNECARE TVT procedure, in case of pregnancy delivery via cesarean section is recommended.
- Postoperatively, the patient is recommended to refrain from heavy lifting and/or exercise (i.e., cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can return to other normal activity after one or two weeks.
- Should dysuria, bleeding or other problems occur, the patient is instructed to contact the surgeon immediately.
- All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected. Defective instruments or instruments that appear to be corroded should not be used and should be discarded.
- As with other incontinence procedures, de novo detrusor instability may occur following the GYNECARE TVT procedure. To minimize this risk, make sure to place the tape tension-free in the mid-urethral position.
- Do not contact the PROLENE® Mesh with any staples, clips or clamps, as mechanical damage to the mesh may occur.
- Do not resterilize GYNECARE TVT device. Discard opened, unused devices.

**ADVERSE REACTIONS**

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.

- As with all foreign bodies, PROLENE® Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE® Mesh is designed to minimize the risk of contamination.
- Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.

**ACTIONS**
Animal studies show that implantation of PROLENE® Mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

**INSTRUCTIONS FOR CLEANING REUSABLE INSTRUMENTS**
**(GYNECARE TVT Introducer, GYNECARE TVT Rigid Catheter Guide)** To ensure the reliability and functionality of the GYNECARE TVT introducer and GYNECARE TVT rigid catheter guide, clean the instruments before initial use and after each procedure. The following are suggested manual and automated methods for cleaning the instruments. Prior to cleaning, the GYNECARE TVT introducer should be separated into its component parts (handle and threaded shaft). The introducer is reassembled after cleaning and before sterilization.

**Manual method**
1. Soak the instrument components in an enzyme cleaner suitable for stainless steel instruments.
2. Wash in a surgical detergent and disinfecting solution at a temperature of 86°F to 95°F (30°C to 35°C). Remove any contamination from body fluids or tissues using a soft brush.
3. Place the instrument components in an ultrasonic bath with fresh detergent solution for approximately 10 minutes or follow the instructions below if using an automatic washing cycle.
4. Rinse thoroughly in a stream of fresh tap water followed by towel drying. The instrument components may be treated with instrument lubricant.

**Automated Method:**
Automatic washing cycles are suitable for stainless steel instruments. One recommended cycle is described below:
- Rinse/Wet Cycle Cold Water – 1 minute
- Wash 176°F (80°C) – 12 minutes
- Rinse Cycle – 1 minute
- Rinse Cycle – 12 minutes
- Final Rinse – 2 minutes
- Rinse with Demineralized water 176°F (80°C) – 2 minutes
- Dry 199.4°F (93°C) – 10 minutes

**STERILIZATION RECOMMENDATIONS FOR REUSABLE INSTRUMENTS**
**(GYNECARE TVT Introducer, GYNECARE TVT Rigid Catheter Guide)**
The GYNECARE TVT introducer and GYNECARE TVT rigid catheter guide are supplied non-sterile. To sterilize, steam autoclave prior to each use. Steam autoclave at a temperature of 270°F to 284°F (132°C to 140°C) for a minimum of 4 minutes (pre-vacuum). It is the responsibility of the end user to assure sterility of the product when using sterilization process recommended, since bioburden and sterilization equipment will vary.

**INSTRUMENT MAINTENANCE**
- GYNECARE TVT Introducer

Before each use, inspect the threaded parts of the inner shaft.
- GYNECARE TVT Rigid Catheter Guide

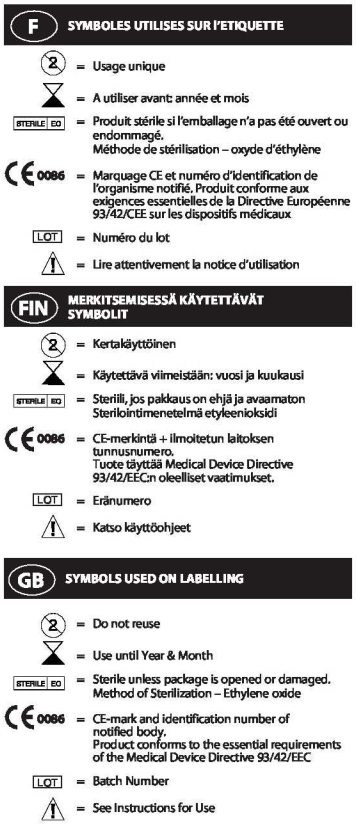
Before each use, inspect the instrument. Check to ensure that the long end which traverses the catheter channel has no sharp edges or burrs.

**HOW SUPPLIED**
The GYNECARE TVT device is provided sterile (ethylene oxide) for single use. Do not re-sterilize. Do not use if package is opened or damaged. Discard opened, unused devices. The reusable GYNECARE TVT introducer and GYNECARE TVT rigid catheter guide are supplied separately and are non-sterile. These accessories are to be cleaned and sterilized prior to each use as described above.

**STORAGE**
Recommended storage conditions for the GYNECARE TVT single use device are below 25°C, away from moisture and direct heat. Do not use after expiry date.

**Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.**

**Legal Manufacturer:**
**ETHICON® Sàrl**
**Rue du Puits Godet 20**
**CH-2000 Neuchâtel**
**Switzerland**


F
SYMBOLES UTILISES SUR L'ETIQUETTE
= Usage unique
= A utiliser avant: année et mois
STERILE EO
= Produit stérile si l'emballage n'a pas été ouvert ou endommagé.
Méthode de stérilisation – oxyde d'éthylène
CE 0086
= Marquage CE et numéro d'identification de l'organisme notifié. Produit conforme aux exigences essentielles de la Directive Européenne 93/42/CEE sur les dispositifs médicaux
LOT
= Numéro du lot
= Lire attentivement la notice d'utilisation
FIN
MERKITSEMISESSÄ KÄYTETTÄVÄT SYMBOLIT
= Kertakäyttöinen
= Käytettävä viimeistään: vuosi ja kuukausi
STERILE EO
= Sterili, jos pakkaus on ehjä ja avaamaton
Sterilointimenetelmä etyleenioksidi
CE 0086
= CE-merkintä + ilmoitetun laitoksen tunnusnumero.
Tuote täyttää Medical Device Directive 93/42/EEC:n oleelliset vaatimukset.
LOT
= Eränumero
= Katso käyttöohjeet
GB
SYMBOLS USED ON LABELLING
= Do not reuse
= Use until Year & Month
STERILE EO
= Sterile unless package is opened or damaged.
Method of Sterilization – Ethylene oxide
CE 0086
= CE-mark and identification number of notified body.
Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC
LOT
= Batch Number
= See Instructions for Use